

MAR 07 2013

5. 510(k) Summary**Contact information****Submitter:**

Mr. Takeshi Yuasa
General Manager, Overseas Regulatory Affairs
Kawasumi Laboratories, Inc.
Shinagawa Intercity Tower B, 9th Floor
2-15-2, Konan, Minato-ku, Tokyo 108-6109, Japan
PHONE: 81-3-5769-2664

Contact:

Mr. Kazuhiko Hashimoto
Kawasumi Laboratories America, Inc.
4723 Oak Fair Blvd.
Tampa, Florida 33610
PHONE: 813-630-5554
FAX: 813-630-5033
E-mail: KHashimoto@kawasumiamerica.com

Date of preparation: 10/29/2012**Device Name:** K-Shield Advantage Port Access Infusion Set**Proprietary name:** K-Shield Advantage Port Access Infusion Set**Common name:** Port Access Products (PAIS series)**Classification Name:** set, administration, intravascular**Product Code:** FPA**Predicate Information**

The proposed K-Shield Advantage Port Access Infusion Set (PAIS) is substantially equivalent in both function and use to the predicate device, Kawasumi Port Access Infusion Set with Anti Needle Stick Protector (K060580 cleared on 06/06/2006). The predicate is a legally marketed device with the same product code as the proposed device.

Device Description

The K-Shield Advantage Port Access Infusion Set (PAIS) is a safety port access device used to administer solutions to a surgically implanted port. This device is designed utilizing a non-coring Huber needle to access the implanted port. The K-Shield Advantage PAIS has an integral safety device intended to protect against accidental needle stick injuries and infection caused by blood borne pathogens. Upon removal from the port, the Anti- Needlestick Protector (ANSP) covers the needle tip protecting against accidental needle stick injuries.

The devices are disposable ethylene oxide sterilized medical devices which are constructed from non-coring needle (Huber needle), wing, tubing (either micro bore or standard bore), clamp, female conical fitting and locking cap. The device has optional injection site (needle injection, needleless access connector (NAC), or no injection site) and/or anti-needlestick protector (ANSP).

Table 1. Table of Possible Device Configurations:

Tubing	Anti Needle Stick Protector	Injection Site
Micro bore	With	Needle injection site
		NAC (Needleless Access Connector)
		without
	Without	Needle injection site
		NAC (Needleless Access Connector)
		without
Standard bore	With	Needle injection site
		NAC (Needleless Access Connector)
		without
	Without	Needle injection site
		NAC (Needleless Access Connector)
		without

Device Characteristics:

The devices are single use, disposable ethylene oxide sterilized medical devices. Sterilization validation was conducted per *EN ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*. The devices are considered blood path, indirect contact per section 5.2.2(a) of ISO 10993-1: 2009 *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*.

Environment of Use:

The PAIS is intended for use at healthcare facilities or in hospitals.

Materials of Use

General type of material used: polypropylene, polyvinylchloride, stainless steel. The materials are evaluated per ISO 10993-1: 2009 *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process* and have been determined to be biocompatible.

Intended Use

The devices are used to administer solutions to a surgically implanted port.

The indications are equivalent to the predicate device.

Technological Characteristics

The device is technologically equivalent to the predicate device. Both devices are safety port access devices used to administer solutions to a surgically implanted port. The devices come in similar sizes and have similar components. Both devices are sterilized under ethylene oxide-gas sterilization.

Performance Data

Bench testing was performed and confirms that the device meets design requirements and specifications. The devices comply with the International standard EN ISO 8536-4: 2007-Infusion equipment for medical use -Part 4: Infusion sets for single use, gravity feed mainly, to be used primarily in a hospital / healthcare facility setting. The devices were evaluated to be safe and effective as a medical device based on design verification test results.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 7, 2013

Kawasumi Laboratories, Incorporated
C/O Ms. Christina Henza
Regulatory Affairs Specialist
Regulatory Compliance Associates, Incorporated
7401 104th Avenue, Suite 160
KENOSHA WI 53142

Re: K123344

Trade/Device Name: K-Shield Advantage Port Access Infusion Set (PAIS)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 11, 2012
Received: January 28, 2013

Dear Ms. Henza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson", is written over a faint, circular official stamp. The signature is fluid and cursive.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Pending → K123344

Device Name: K-Shield Advantage Port Access Infusion Set (PAIS)

Indications For Use: The devices are used to administer solutions to a surgically implanted port.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sajjad H. Syed

Digitally signed by Sajjad H. Syed
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Sajjad H. Syed,
0.9.2342.19200300.100.1.1=2000601742
Date: 2013.03.05 13:23:33 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123344

Page 1 of 1